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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,339	01/26/2004	Shawn R. Feaster	034047.003DIV1 (W 00-23B)	7108
53502 7590 12/28/2010 OFFICE OF THE STAFF JUDGE ADVOCATE (SKS) U.S. ARMY MED. RESEARCH & MATERIEL COMMAND 504 SCOTT STREET ATTN: MCMR-ZA-J (MS. ELIZABETH ARWINE) FORT DETRICK, MD 21702-5012			EXAMINER SHEN, BIN	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 12/28/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/763,339	<b>Applicant(s)</b> FEASTER ET AL.	
	<b>Examiner</b> BIN SHEN	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29-36 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) 31-34 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29,30,35 and 39-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 7, 2010 has been entered.

### **Status of the Claims**

Claims 29-36, 39-42 are currently pending. Claims 31-34, 36 are withdrawn from further consideration.

Claims 29, 30, 35, 39-42 are presented for examination on the merits.

Benefit of priority is to 5/5/2000.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 is rendered vague and indefinite by the word "a cartridge...the number of substrates...is one more than the number of proteins...". The term "cartridge" is not defined by the claim or the specification by the number of substrates included, thus it is unclear if the device comprises a series of cartridges with various numbers of substrates because it is unlikely to add one more substrate to the cartridge after knowing the number of enzymes to be analyzed by the device. Furthermore, the plurality of proteins/enzymes measured by the device is variable, therefore "a cartridge comprising...is one more than the number of proteins..." is also a

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variable, thus the “cartridge” is indefinite because it is unclear what the substrate components are in the cartridge.

## Maintenance of Rejections:

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 30, 35, 39, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by London (1995).

London teaches a field kit (Test-Mate OP kit) for estimation of cholinesterase in whole blood using two substrates: butyrylthiocholine and acetylthiocholine (in reagent dispenser, page 59, left column, 2<sup>nd</sup> full paragraph). For details of the Test-Mate OP kit and what is in the reagent dispenser see Magnotti, 1988, page 317, 3<sup>rd</sup> and 4<sup>th</sup> full paragraph, and page 318, step2 of "Field kinetic method").

Therefore, London teaches a device for detecting, measuring or monitoring cholinesterase in blood sample comprising **a cartridge** (read as reagent dispenser) with plurality of substrates (page 59, left column, 2<sup>nd</sup> full paragraph, lines 1-3; **a detector** for detecting reaction rates (colorimeter, page 59, left column, 2<sup>nd</sup> full paragraph, line 5); **software** for calculating protein concentration (page 59, left column, 2<sup>nd</sup> full paragraph, line 5, **Claim 29**); the cartridge/kit comprises reagent, buffer standard for measuring the reaction rates (see substrate for the enzymes on page 59, left column, 2<sup>nd</sup> full paragraph, lines 1-3, since the field kit estimate cholinesterase therefore inherently contains all necessary reagent/buffer/standard for measuring the reaction rates, **Claim 30**); wherein the kit is capable of detecting cholinesterase including plasma cholinesterase and erythrocyte cholinesterase (plurality of proteins, page 59, left column, 2<sup>nd</sup> full paragraph, lines 1-2, **Claim 35**); the field kit (Test-Mate OP kit, page 57, right column, 3<sup>rd</sup> full paragraph, lines 8-9) is inherently hand-held for easy application (**Claim 39**).

Therefore, London also teaches a device for detecting, measuring or monitoring cholinesterase in blood sample comprising **a cartridge** (read as reagent dispenser) with two substrates (butyrylthiocholine and acetylthiocholine) which is one more than at least one protein/enzyme/cholinesterase; **a detector** for detecting reaction rates (colorimeter, page 59, left column, 2<sup>nd</sup> full paragraph, line 5); **software** for calculating protein concentration (page 59, left column, 2<sup>nd</sup> full paragraph, line 5, **Claim 42**).

Applicant's arguments filed 7/7/2010 have been fully considered but they are not persuasive.

Applicant argues that London does not teach or suggest a device which has a cartridge containing a plurality of substrates wherein the number of substrates is one more than then number of the protein being assayed.

It is the examiner's position that London teaches a field kit (Test-Mate OP kit) for estimation of cholinesterase using two substrates: butyrylthiocholine and acetylthiocholine, therefore the number of substrate is one more than the protein assayed. Furthermore, it is unclear if the device comprises only one cartridge (see above 112-2<sup>nd</sup> rejection) to assay for a fixed number of proteins/enzymes. Thirdly, the claimed device as written does not have to assay n+1 substrates to measure n proteins because the number of proteins assayed is only the intended use of the device, especially in claim 29, and thus does not provide patentable limitation for the device.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 29, 40 are again rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of London and Jacobs (1993).

London's teachings anticipate claims 29 as above.

London does not teach cartridge triggers device automation when inserted.

Jacobs teaches a blood analyzer with an insertable cartridge (page 1891, left column, 1<sup>st</sup> full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify/automate the device of London by using a insertable cartridge to trigger the automation of the device (**Claim 40**) because Jacobs teaches a cartridge that can be inserted in the device. One would have been motivated to automate the device because Jacobs et al. specifically described a cartridge in a blood analyzer and one of ordinary skill in the art has good reason to automate the device by trigger the automation by inserting the cartridge for anticipated success in view of Jacob's teaching of an insertable cartridge for a blood analyzer.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed 7/7/2010 have been fully considered but they are not persuasive.

Applicant argues that neither London nor Jacobs teach/suggest a cartridge having a plurality of substrates, wherein the number of substrates is one more than the number of proteins.

It is the examiner's position that London teaches a field kit (Test-Mate OP kit) for estimation of cholinesterase using two substrates: butyrylthiocholine and acetylthiocholine, therefore the number of substrate is one more than the proteins assayed. Furthermore, the claimed device as written does not have to assay  $n+1$  substrates to measure  $n$  proteins because the number of proteins assayed is only the intended use of the device, especially in claim 29, and thus does not provide patentable limitation for the device.

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***Conclusion***

No claim is allowed.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571) 272-0925.

*B Shen*

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/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657